EXHIBIT 1

EXHIBIT A

Filed with Redactions

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**No. 1:19-md-2875-RBK**

EXPERT DECLARATION OF JOHN L. QUICK

I. EXECUTIVE SUMMARY

1. My name is John L. Quick. Plaintiffs' counsel in this case have requested that I evaluate whether certain actions or inactions by the Manufacturer Defendants' (both Active Pharmaceutical Ingredient ("API") and Finished Dose Formulation ("FDF") are in compliance or non-compliance with the Federal Food Drug and Cosmetics Act ("FDCA") and Current Good Manufacturing Practices ("CGMPs") promulgated thereunder and whether their issues would have impacted all Valsartan product equally.

2. The materials I reviewed for the purposes of this Class Expert Declaration are attached and appended as Exhibit A.

3. I reserve the right to modify or supplement this Declaration if and when appropriate, particularly based upon additional information, data, documents, or other evidence, of which I am made aware subsequently. I expressly reserve my right to supplement or modify my opinions expressed herein.

II. QUALIFICATIONS AND EXPERIENCE

4. A copy of my current Curriculum Vitae is attached as Exhibit B.

5. I hold an undergraduate degree in Chemistry (1966) from Indiana University in Bloomington, Indiana and an MBA (1972) from the Northwestern University, Kellogg School of Management.

6. From 1966 to 2003, I held various positions at Baxter International. Pertinent to my opinion here, in 1986, I became the Vice President Quality and Regulatory responsible for all quality and regulatory matters associated with Baxter's drug manufacturing facilities. In 1998, I was promoted to Corporate VP Worldwide Quality/Regulatory for all Baxter operations reporting to the Chairman and CEO. I held this position until July 2003.

7. In July 2003, I retired from Baxter and became an independent Quality/Regulatory consultant, a position that I hold currently.

8. [redacted]

a. [redacted]

9. Over the past 15 years, I have conducted numerous quality system audits on API manufacturers on behalf of finished drug manufacturers. These audits have occurred in China, India, various counties in Europe, Canada and the United States.

III. COMPENSATION

10. I am being compensated for my services in this litigation at a rate of $400 per hour and $500 per hour for testimony, depositions and trial work.

IV. PRIOR TESTIMONY

11. I was deposed on January 23, 2020, as an expert witness in the case of *Davol, Inc., Polypropylene Hernia Mesh Product Liability Litigation*, MDL Docket No. 2846 (Southern District of Ohio).

V. SUMMARY OF OPINIONS

A. FDA APPROVAL PROCESS OF PHARMACEUTICALS

12. All prescription drug products (non over the counter drugs) must go through a pre-approval process by the Food and Drug Administration ("FDA). Depending upon the drug product, it can take 10-15 years to go through development and ultimate approval by the FDA. Most new drugs would go through clinical studies (Phase I, Phase 2 and Phase 3) which would require the submission of an Investigational New Drug Application and approval by the FDA.

- Phase 1 – Establishes a drug's safety profile
- Phase 2 – Assesses the drug's effectiveness
- Phase 3 – Large numbers of patients are monitored to determine effectiveness and identify potential side effects. Different types and age ranges of patients are typically evaluated.

13. Following clinical studies, the applicant would submit a New Drug Application (NDA) for review and approval. The NDA is the official request for FDA approval. All appropriate data is included in the NDA.

14. The FDA will review the product labeling including the package insert. The FDA may involve an Advisory Board who may meet to discuss the NDA and may meet with FDA reviewers.

15. The FDA will also determine the compliance status of the manufacturing plant(s) that would manufacture the drug product. In most cases for a new drug product, this will involve a pre-approval inspection (PAI) of the facility(ies). If the facilities have an unacceptable prior inspectional classification, typically OAI (Official Action Indicated), the FDA will not typically approve the application until the matters associated with OAI classification are resolved.

B. GENERIC DRUG APPROVAL

16. In the most simplified terms, a generic drug is a copy of a brand name drug that went through a prior approval. The FDA has a FDA Fact Sheet[1] which details what the drug

[1] FDA Fact Sheet –"What's involved in reviewing and approving generic drug applications" https://www.fda.gov/media/99163/download (last accessed November 3, 2021).

application must demonstrate which includes the following: (Several references to the FDA Fact Sheet are indicated in quotes.)

a. **"Pharmaceutically Equivalent":** The applicant must show that the drug is the same type of product such as a tablet or an injectable and uses the same time release technology (such as immediate-release) meaning for immediate effect of the drug, or extended-release, meaning one that is intended do slowly release the active ingredient over time.

b. **Manufacturer is capable of making the drug correctly**: Different companies may be involved. One company may be the manufacturer of the active ingredient (API) and another company may be manufacturing the finished dosage form. There may be different companies involved in different aspects. The generic drug applicant is ultimately responsible for all aspects of the finished drug product including the actual API manufacture. The FDA may well inspect an active ingredient manufacturer as well as the finished dosage manufacturer. [2]

c. **Manufacturer is capable of making the drug consistently:** Generic drug manufacturers must explain how they intend to manufacture the drug and provide evidence that each step of the manufacturing process will produce the same result each time. FDA reviewers will study those procedures and, in most cases, will conduct a pre-approval inspection to verify the drug manufacturer is capable of making the drug consistently and to check that the information submitted to the FDA is accurate.

d. **Active ingredient is the same as that of the brand:** As part of the application process the generic drug companies, "must provide evidence that shows that their active ingredient is the same as that of the brand-name drug they copy".

e. **Inactive ingredients of the drug are safe:** From the FDA Fact Sheet on Generic Drugs, "[s]ome differences, which must be shown to have no effect on how the drug functions, are allowed between the generic drug and the brand. Generic drug

[2] However, it is important to note that for the purposes of regulatory authorities, the finished dose maker is ultimately responsible for all aspects of their drug product, including the active ingredient.

manufacturers must submit evidence that all ingredients used in their products are safe, and FDA must review that evidence."

f. **Drug does not break down within expiration period:** Drugs will break down, over time. Both brand-name drugs and generic drugs must submit stability studies to show that the drug products are stable through-out the expiration period.

g. **Label is the same as the brand-name's drug label:** The drug information label for the generic drug is to be the same as the brand.

17. The manufacturer is responsible for continuing to manufacture the process in the manner delineated in any relevant FDA approved processes and is required to manufacture these products in compliance with Current Good Manufacturing Practices ("CGMPs") on a continual basis. These responsibilities extend to the entire life cycle of the product, for as long as the product is being sold to consumers.

18. FDA states on its website, www.fda.gov, "[a]ll approved products both innovator and generic, are listed in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" Orange Book. [3]

19. The Orange Book lists all drugs approved by the FDA and their therapeutic equivalents (if any). The FDA approves generic drugs that the manufacturer demonstrates to the FDA are therapeutically equivalent to an already-approved brand medication.

20. The requirements for therapeutic equivalence are clearly stated in the Orange Book preface: "FDA classifies as therapeutically equivalent those drug products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an

[3] https://www fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda (last accessed November 3, 2021).

appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations."[4] While the Active Ingredients (API) may vary in comparison to API from those of their brand counterparts, they must be shown not to affect "the safety or efficacy of the proposed drug product"[5] in order to receive approval and be listed in the FDA Orange Book.

C. ADULTERATED AND MISBRANDED DRUG PRODUCTS

21. The FDA has defined "adulterated" drug products in 21 U.S. Code § 351.

22. In that code, a drug shall be deemed adulterated "(1) [i]f it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." [6]

23. While adulteration is generally considered to occur in circumstances where a drug has become contaminated with substance that is injurious to health (such as the adulteration that occurred with the Defendants' valsartan that contained NDMA and NDEA), it is obvious that the regulations also take a much broader approach to their view of adulteration, including a manufacturer's compliance with cGMP which might prevent products from becoming contaminated in the first instance.

24. Under the regulations, the actual product does not have to be actually contaminated if the product was manufactured in a facility that did not meet CGMP requirements in such a way

[4] FDA, Orange Book Preface (https://www fda.gov/drugs/development-approval-process-drugs/orange-book-preface) (last accessed November 3, 2021).

[5] 21 CFR 314.94(9)(ii).

[6] 21 U.S. Code § 351.

that the manufacturer could not assure that their products met their specifications, as determined by the FDA.

25. The FD&C Act "requires that the methods, facilities and controls used for manufacturing, processing, packing, or holding drugs conforms with CGMP to assure the identity, strength, quality, and purity of the resulting drug products. For a facility to be in compliance with CGMP, it is not enough that the finished drug products or the APIs used to manufacture such finished drugs, conform to specifications and that the testing for such products does not suggest any trends toward being out of specifications. Rather a facility must have in place systems that ensure proper design, monitoring, and control of manufacturing processes and facilities."

26. The key aspect is that the if the finished drug facility or API manufacturing facility does not have in place, "systems that ensure proper design, monitoring, and control of manufacturing processes and facilities," the facility is not compliant with CGMP and thus all products in the facility would be considered to be adulterated. This would extend to all pills produced at the facility.

27. According to Section 502 of the FD&C Act, a drug product may be declared misbranded if the label is false or misleading" in a way which "fails to reveal" facts material with respect to consequences which may result from use of the article.[7]

28. The fact that NDMA and/or NDEA (and other contaminants) were present in the API and ultimately in the finished drug product results in the product as being adulterated.

29. The fact that the Manufacturer Defendants' valsartan products were manufactured in facilities that did not have the appropriate CGMP quality assurance activities in place, which would have prevented the NDMA and/or NDEA from even being present in the product in the first place, results in the Defendants' Valsartan products being adulterated.

30. Because the presence of NDMA and/or NDEA was not revealed in the labeling, advertisements and/or patient booklets given to consumers at the time of dispensing, this also resulted in the Defendants' Valsartan products being misbranded.

[7] 21 CFR 202.1(d)(5)(iii).

D. CURRENT GOOD MANUFACTURING PRACTICES OVERVIEW

31. FDA defines CGMP for both finished drug products and active pharmaceutical Ingredients (APIs). The"C" in CGMPs as standing for "Current" requiring companies to use technologies and systems that are up to date in order to comply with the regulations and require ongoing compliance with current best practices.

32. FDA's official position [8] regarding CGMPs is that if a company is not complying with CGMP regulations, any drug it makes is considered "adulterated" under the law.

33. CGMP applies to both finished drug products and APIs. FDA in its API Process Inspection Manual states, "FDA has long recognized that the CGMP requirements in the good manufacturing practice regulations for finished pharmaceuticals (21 CFR 210 and 211) are valid and applicable in concept to active pharmaceutical (API) manufacturing."[9]

34. As the FDA has repeatedly stated [10] "[i]f one of the six systems (Quality, Laboratory, Production, Facilities & Equipment and Packaging & Labeling) is out of control, the firm is considered out of control." The FDA presentation went on to say, "A system is considered out of control based on GMP deficiencies which suggest lack of quality". FDA has formalized this in the Active Pharmaceutical Ingredient (API) Process Inspection Manual to further state, "A firm is not in a sufficient state of control if any one system as defined in this program (same as stated above), is found to be significantly non-compliant with CGMPs such that the quality, identity and purity of the API resulting from that system cannot be adequately assured. Documented CGMP deficiencies provide the evidence for concluding that a system is not operating in a state of control."[11]

[8] "Facts About the Current Good Manufacturing Practices (CGMPs) – https://www fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps (last accessed November 3, 2021)
[9] FDA Compliance Program Guidance Manual 7356.002F, September 11, 2015, page 4.
[10] FDA Power Point Presentation by Robert C. Horan, New York District, *"FDA cGMP Inspection, Peking University 2005"*
[11] FDA Compliance Program Manual 7356.002F, September 11, 2015, page 7.

35. Finished Drug Products and APIs each have their own set of cGMP requirements[12] related to their specific manufacturing practices. However, these requirements are largely aligned, and for the most critical aspects, they are the same.

36. FDA employs a number of "Guidances" on how to interpret the regulations. The expectation from FDA is that regulated entities will follow the appropriate Guidances. Most FDA "Guidances" have the following wording, "You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations." FDA also offers industry the opportunity to discuss an alternate approach. In the absence of the firm having such discussions with the FDA to gain acceptance of alternative approaches, the firm should in fact adhere to the Guidances as to how be in compliance with CGMPs. Throughout this section, the appropriate Guidances are referenced.

37. The following discusses the most relevant aspects of CGMP as it relates to the manufacture of drug products, and are examples of corporate-level, overarching CGMP obligations that would impact all pharmaceutical products manufactured from a particular facility equally.

i. ORGANIZATIONAL STRUCTURE

38. The expectation is that there will be an independent quality organization that does not report to the manufacturing function. The quality organization must be adequately staffed with qualified individuals who are qualified on the basis of their education, training, experience or any combination thereof. Such qualifications must be documented.

39. In most regulated companies, the head of quality would report to the CEO, President or other high-level official of the company. If the head of manufacturing and the head of quality are not viewed as having equivalent reporting positions, this may diminish the position of quality. Business decisions should never impact quality decisions. The business consequences should only be discussed once the quality decision has been made by the quality function.

[12] Finished Drug Product CGMP obligations can be found at 21 CFR 210 and 211, while API cGMP obligations can be found at Q7 guidance.

ii. RESPONSIBLE AND TRAINED QUALITY DEPARTMENT

40. The quality department must have the responsibility and authority to approve all components, drug product containers, closures, in-process materials and the authority to review production records and to assure that any errors or deviations are properly investigated. The quality function will approve or reject finished products prior to release. The quality function is responsible for approving or rejecting drug products manufactured under contract by another entity. The quality function must have the responsibility for approving or rejecting all procedures impacting on the identity, strength, quality and purity of the drug product. The responsibilities of the quality function must be in writing and such procedures must be followed.

41. Typically, the quality function would be responsible for supplier qualification and quality agreements with suppliers. Typically, the quality function would be responsible for product recalls. The decisions of the quality function should never be overridden by higher levels of management.

42. All employees involved in quality/manufacturing should undergo initial CGMP training and additional training at periodic intervals. Such training should be documented and verified as being effective.

iii. COMPREHENSIVE QUALITY MANAGEMENT SYSTEM

43. The expectation for pharmaceutical drug manufacturing quality systems is detailed in the FDA Q10 Guidance.[13] Many aspects of CGMP which are not specifically detailed in 21 CFR 211 are described in the Q10 Guidance and the FDA API Process Inspection Manual, 7356.002F. FDA notes, "These areas are not limited to the final APIs, but may also include starting materials and intermediates."[14] This includes such elements as:

44. **Standard Operating Procedures ("SOPs"):** The company should have established procedures for all aspects relative to drug products which would include (not all inclusive but pertinent examples):

[13] FDA Guidance Q10 "*Quality Systems Approach to Pharmaceutical CGP Regulations*," September 2006.
[14] FDA Guidance Q10 "*Quality Systems Approach to Pharmaceutical CGP Regulations*," September 2006, Appendix A, page 24.

- Risk Management
- Incoming raw materials and release
- Deviations/nonconformances
- Out-of-Specification (OOS)
- Annual Product Reviews
- Change Control
- Product Complaints
- Corrective and Preventative Actions ("CAPAs")
- Process Validation
- Stability Studies
- Reprocessing

45. All SOPs must be approved by the quality function. Any changes to such procedures must be approved by the same quality function.

46. The number one citation by FDA year after year is the following, "Procedures not in writing, fully followed".[15]

47. **Risk Assessment:** FDA routinely requires both manufacturers of APIs and finished drug products to provide risk assessments. FDA has issued Guidance Q9 "Quality Risk Management" which details how to conduct a risk management process. FDA has cited pharmaceutical firms for the failure to have an effective risk management process.[16] In such cases, the FDA is stating in the Warning Letter, "Your firm's quality systems are inadequate" and is referring the firm to the Q9 Guidance document on Quality Risk Management.

48. From a very specific standpoint, FDA in its Guidance, "Control of Nitrosamine Impurities in Human Drugs" [17] has very specifically addressed the matter of risk assessments with the following:

a. "Assess the risk of nitrosamine impurities in APIs, marketed products, and products under approved and pending applications. Risk Assessments should be conducted in a timely manner based on the prioritization of drugs. Manufacturers do not need to submit risk assessment documents to the Agency, but they should retain these documents so that they are available if requested."

[15] FDA website, www.fda.gov/ICECI/inspections/ucm250720 htm (last accessed November 2, 2021).
[16] FDA Warning Letter, Akorn, Inc. June 13, 2019, and US Pharmaceuticals, Inc. June 6, 2019.
[17] FDA Guidance, *"Control of Nitrosamine Impurities in Human Drugs,"* February 2021, page 11.

49. **Change Management System:** CGMPs expect that a finished drug manufacturer as well as an API manufacturer will have an effective change management system.[18] All changes should be evaluated by a company's established change management system. While 21 CFR 211 has no direct reference to change control, change control is implied in 21 CFR 211.100(a) and 21 CFR 211.160(a). Section 21 CFR 211.100(a) requires that changes in production procedures and process controls be reviewed by the appropriate organizational units and the quality control function. In the case of 211.160(a), there is a requirement for a similar review and approval for changes related to laboratory controls, sampling plans, specifications and analytical test methods.

50. The manufacturer should have an approved, thorough and comprehensive SOP that details the steps for change control.

51. Quality Risk Management should be employed to evaluate the proposed changes. The extent of risk evaluation should be commensurate with the level of risk.

52. Proposed changes should be evaluated relative to regulatory filings and whether such changes require a notification and approval by the FDA.

53. Changes should be evaluated by expert teams with the appropriate expertise and knowledge. In many cases, this may involve bringing in outside expertise.

54. All changes prior to implementation should be reviewed and approved by the quality function.

55. Any such changes should be evaluated to determine if the change impacts any equipment qualifications or process validations. A decision should be made relative to the need ro redo any such equipment qualifications and/or process validations prior to implementing the change(s).

56. After implementation, an evaluation of the change should be undertaken to confirm the change was effective and that there was no negative impact on product quality.

57. **Process Validation:** Process validation is a requirement for drug products and APIs and is described in the FDA Guidance, "Process Validation: General Principles and

[18] FDA Guidance *"Quality Systems Approach to Pharmaceutical CGMP Regulations,"* September 2006, page 11.

Practices". All processes generally should be validated. Any changes in the process should be evaluated to determine if the change requires a new validation.

58. **Corrective and Preventative Action.** While not specifically mentioned in 21 CFR 211, Corrective and Preventative Actions ("CAPA") have become an expectation for API and finished dose manufacturers. CAPA is specifically detailed in the Q10 Guidance, "Pharmaceutical Quality System."[19]

59. CAPAs would typically be initiated for adverse trends or significant adverse events or inspectional issues. The key to an effective CAPA is timeliness and the determination of CAPA effectiveness.

60. **Deviations:** Addressing deviations is an important element of CGMPs as it relates to 21 CFR 211. [20]

61. Deviations must be addressed in a timely manner and must be documented. Deviations should be properly investigated and should be approved by the quality function.

62. **Investigations:** Investigations are a key element of CGMP. FDA 21 CFR 211.22 states, the responsibility of the Quality function is, "if errors have occurred, that they have been fully investigated".

63. Investigations should be initiated for deviations, non-conformances and OOS results.

64. **Supplier Qualification:** Supplier qualification and control is critical for drug manufacturers. The FDA issued Guidance on Contract Manufacturing.[21] The Guidance covers both manufacturers of finished drug products as well was API manufacturers. FDA in this guidance defines "owners" as manufacturers of APIs, drug substances, in-process materials and finished drug products. The FDA specifically states, "When an owner uses a contract facility, the owner's quality unit is legally responsible for approving or rejecting drug products manufactured

[19] FDA Guidance Q10, *"Pharmaceutical Quality System,"* page 9.
[20] 21 CFR 211.86 (Deviations from the use of approved components); 21 CFR 211.100 (Deviations from written production and process procedures); 21 CFR 211.111 (Deviations from established time limits); 21 CFR 211.150 (Deviations from distribution procedures).
[21] FDA Guidance "Contract Manufacturing Arrangements for Drugs: Quality Agreements," November 2016.

by the contract facility including final release." [22] FDA also notes that in Q7, the term "company" is used rather than "owner" and is used to refer to an API manufacturer.

65. FDA expects owners to evaluate contract facilities to ensure that contractor sites comply with CGMP for specific operations. The "evaluation" would typically consist of an on-site audit prior to qualifying the contract facility and periodic audits following the initial audit.

66. FDA also expects that owners have written quality agreements with contractors that define manufacturing responsibilities in detail, including the quality measures, obligations and responsibilities, of each party. The written agreements should also define considerations for subcontracting; describe how changes to processes, equipment, methods, and specifications will be managed; and permit the owner to audit its contractor's facilities for compliance with CGMP.[23] Such audit reports would be issued to audited facility with a deadline of usually no more than 30 days to respond with corrective actions.

67. The Guidance refers specifically to Risk Management and references Q9 with the expectation that risk management will be employed.

68. A key point is that a quality agreement between the parties cannot exempt owners or contract facilities from statutory or regulatory responsibilities to comply with applicable CGMP, regardless of whether or not the quality agreement specifically discusses these CGMP requirements.

69. The FDA specifically states, "the owner remains responsible for ensuring its products are made in compliance with CGMP even when a quality agreement assigns a particular manufacturing activity to the contract facility."[24]

70. **Proper Oversight of Use of Recovered Solvents in Drug Manufacturing:** Recovered solvents has been a focus of the FDA.

71. The FDA expects Drug Manufacturers to appropriately validate their methods for recovering solvent. Specifically, the FDA states, "FDA expects API manufacturers to apply

[22] 21 CFR 200.10(b) and 211.22(a).
[23] FDA Guidance "Contract Manufacturing Arrangements for Drugs: Quality Agreements," November 2016, page 4.
[24] FDA Guidance "Contract Manufacturing Arrangements for Drugs: Quality Agreements," November 2016, page 12.

CGMPs to the API process beginning with the use of starting materials, and to validate critical process steps that impact the quality and purity of the final API."[25]

72. Additionally, the FDA expects Drug Manufacturers to test and compare recovered solvents to an established standard. Specifically, the FDA states, "Solvents can be recovered and reused in the same processes or in different processes provided that solvents meet appropriate standards before reuse or commingling."[26]

73. The FDA also expects that a manufacturer should have established impurity profiles for recovered solvents.

74. Any extraneous peaks in recovered solvents should be thoroughly investigated.

75. Where appropriate, a risk assessment process should be employed to analyze whether there is a risk associated with the use of a particular recovered solvent, and solvent recovery process in the manufacture of a drug product.

E. FDA Oversight In Assessing Whether Manufacturers Are Meeting Their CGMP Obligations

76. While the Drug Manufacturers are obligated to ensure for themselves that they are meeting the current CGMP requirements, the FDA will at times conduct inspections of the facilities to ensure for themselves that the Drug Manufacturers are meeting their own obligations.

i. Inspections

77. FDA generally conducts the following types of inspections:

- Pre-Approval inspections
- Routine inspections
- Compliance Follow-up inspections
- For-cause inspections

[25] FDA Compliance Program Guidance Manual, API Process Inspection, September 11, 2015, page 4.
[26] FDA Compliance Program Guidance Manual, API Process Inspection, September 11, 2015, page 27.

78. Prior to approving any NDA or ANDA Drug Application, the FDA may conduct a Pre-Approval Inspection (PAI) of a Drug Manufacturer's facility to confirm that a manufacturing establishment named in a drug application is capable of manufacturing a drug and that submitted data are accurate and complete.[27]

79. PAI inspections are risk based and based on a number of circumstances. For example, from a facility risk standpoint: [28]

- GMP issues relevant to application product
- Recent FARs (Field Alert Reports) relevant to application product
- Recent recalls relevant to application product
- Numerous applications filed at once

80. FDA will conduct routine inspections that take place following approval that are intended to evaluate commercial scale processes, process validation, manufacturing changes and any changes in perceived product risks. FDA will generally focus on several key quality systems. Typically, these would be every two years but could be on a shorter or longer frequency.

81. FDA will conduct follow-up inspections to review the actions taken by a firm or manufacturer in response to a previous inspection that resulted in a significant FDA 483 or Warning Letter.

82. FDA will conduct a "For Cause" inspection to investigate a specific problem or issue but such inspections can branch out to a more general inspection.

83. "For Cause" inspections typically are more in-depth inspections and usually have a special focus. For cause inspections can be the result of a recall, disgruntled employee, product complaint or any number of other issues.

[27] "*FDA's Pre-Approval Inspection (PAI) Program and How to prepare for a successful outcome,*" Denise DiGlulio, FDA Facility Reviewer, Office of Process and Facilities, Fall 2015.
[28] "*FDA's Pre-Approval Inspection (PAI) Program and How to prepare for a successful outcome,*" Denise DiGlulio, FDA Facility Reviewer, Office of Process and Facilities, Fall 2015.

84. In the case of the valsartan contamination for example, the FDA inspected finished drug manufacturers, API manufacturers and key contractors such as those that processed solvents. This practice is common to all products produced under such circumstances.

II. FORM 483

85. At the conclusion of an inspection, if the FDA investigator has observed any conditions that are deemed to be objectionable which in the investigator's judgement indicate that a FDA regulated product may be in violation of FDA's requirements, the FDA investigator will issue a FDA Form 483.[29]

86. The FDA Form 483 notifies the company's management of objectionable conditions. The FDA's official position regarding Form FDA 483s is that there may be other objectionable conditions that may exist at the firm that are not cited on the FDA Form 483. FDA's position is that "companies are responsible to take corrective action to address the cited objectionable conditions and any related non-cited objectionable conditions that might exist." [30]

87. The normal process for a firm who has received a Form 483 is to respond although there is no statutory requirement to respond to the 483. The FDA's stated position is that if a firm expects the FDA to consider its response to a FDA Form 483, it must respond within 15 business days.

88. The FDA 483 response is extremely important to prevent additional actions by the FDA. The response should be thorough and should provide evidence of corrective actions through attachments. If not all actions can be completed within the 15 business days, the firm should state that an update will be provided, usually within 30 days, which will include the identified evidence. It is advisable to continue periodic updates until all corrections have been completed.

89. FDA classifies FDA inspections into three categories:

[29] "FDA Inspection Observations," https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations (last accessed November 4, 2021).
[30] "FDA Form 483 Frequently Asked Questions," https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last accessed November 4, 2021).

- NAI No Action Indicated
- VAI Voluntary Action Indicated
- OAI Official Action Indicated

90. No Action Indicated and Voluntary Action are the most common FDA inspectional classifications. In these situations, the FDA will allow the firm to address any observations that resulted in an FDA 483 and will verify in the next inspection.

91. In the case of an OAI, FDA almost certainly will take an action which could be any one of a number of actions:

- Warning Letter
- Seizure
- Regulatory Meeting
- "Recommendation" to cease manufacturing and recall product
- Consent Decree

92. In the event of an "OAI" finding, the most common action by the FDA would be to issue a Warning Letter to the firm.

93. When the FDA classifies a FDA inspection as OAI (Official Action Indicated) the classification applies to all products manufactured within that facility. The specific wording in the FDA form letter to the company regarding an OAI inspection (regardless of any additional action) is the following, "Based on this inspection, this facility is considered to be in an unacceptable status of compliance with regards to current good manufacturing practice (CGMP).[31]

III. WARNING LETTER

94. If the Drug Manufacturer does not satisfactorily explain and provide corrective actions and provide evidence to the observations made by the FDA, or if the observations are particularly serious, or if there are repeat observations the FDA may well issue a Warning Letter

[31] https://www fda.gov/files/drugs/published/OAI-90-Day-Decisional-Letter.pdf (last accessed November 4, 2021).

95. A Warning Letter is very serious and there must be a response to the FDA usually within 15 days. An FDA Warning Letter will become public knowledge with the FDA releasing the Warning Letter on its website. The FDA in the decision as to whether to issue a Warning Letter will consider the FDA investigator's report, the EIR (Establishment Inspection Report) and the firm's response to the FDA Form 483. The FDA in the Warning Letter will cite the violations and will specifically detail what the FDA expects in a response. This may include specific documents, a CAPA, the recommendation for the firm to engage outside independent consulting expertise. In some situations, the FDA may request a Regulatory Meeting.

F. CORPORATE QUALITY MANAGEMENT APPLIES TO ALL PRODUCTS MANUFACTURED AT A FACILITY

96. The FDA states, "A robust product quality system (PQS) is critical to assuring drug products are manufactured to meet the desired quality and performance attributes. PQS is the key system evaluated during FDA inspections and is also key in providing FDA confidence that appropriate science and risk based support information is used to make decisions."[32]

97. Because the quality system is the system that guides all the manufacturing operations at a given facility, it is necessarily true that the successes (or failures) of the overall quality system at a given facility are the types of corporate level quality assurance activities that would necessarily impact each and every product that the facility manufactures.

98. This is confirmed by the FDA enforcement actions during inspections. While the FDA may inspect a facility for a specific drug application for a product, if the FDA observes deficiencies with the overall corporate level quality activities at that facility, it raises concerns about all drugs manufactured at that facility. FDA's stated position is, "[i]f a company is not complying with CGMP regulations, any drug it makes is considered 'adulterated' under the law."[33]

[32] FDA Presentation, *"The Pharmaceutical Quality System (PQS)*," Robert Iser, FDA Office of Process & Facilities/OPQ/CDER, July 15, 2015.
[33] "Facts About the Current Good Manufacturing Practices (CGMPs)," https://www fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps (last accessed November 3, 2021).

99. For example, in the context of the FDA's criminal sanctions against Ranbaxy, the FDA prevented all products manufactured at a set of manufacturing facilities from entering the United States, even though they only observed issues with a set of specific drug products. [34]

100. This is because deficiencies observed with the overall quality management system would implicate the competence of the quality management system to provide oversight for all of the products manufactured at that facility.

G. Evidence of Defendants' Non-Compliance with CGMPs

101. I have reviewed a a set of documents related to Defendants' Non-Compliance with CGMPs in order to determine whether these examples of non-compliance with CGMPs are the type that would impact and be common to every Valsartan product purchased by the Class Members.

102. After reviewing this these documents, I have determined that the types of CGMP Compliance issues observed by the FDA and related to the manufacture of their Valsartan Products are the types of compliance issues that would impact all the Defendants' Valsartan Products.

i. Evidence Common to the Class of Defendant ZHP's Non-Compliance with CGMPs

103. I have reviewed the documents which have detailed the enforcement actions that FDA has taken in regard to ZHP in the wake of the recall of product for nitrosamines, as well as several key corporate quality documents and the deposition testimony of key quality assurance personnel.

1. ZHP's Failure to Conduct a Risk Assessment Associated with the Manufacturing Change for Valsartan API

104. [redacted]

[34] https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false (last accessed November 2, 2021).
[35] ZHP01427917 (August 2018 FDA Establishment Inspection Report).

[redacted]

[36] ZHP00000161 (translation provided to me by Counsel), page 2.
[37] ZHP01427917 (August 2018 FDA Establishment Inspection Report), page 23.
[38] ZHP01427917 (August 2018 FDA Establishment Inspection Report), page 26.
[39] ZHP01427917 (August 2018 FDA Establishment Inspection Report), page 22.
[40] ZHP00000417 (SMP-023.03) (page 11 of 17).
[41] ZHP01427950.

110. [redacted]

2. ZHP'S FAILURE TO ADEQUATELY ASSESS DEVIATIONS, UNKNOWN PEAKS, AND OTHER ABERRANT TEST FINDINGS.

113. [redacted]

[42] Dep. Tr. Jucai Ge 227:5-23.
[43] Dep. Tr. Min Li 107:12-14.
[44] ZHP01748896.
[45] ZHP02630924, ZHP02118072, ZHP02118712.
[46] Dep. Tr. Jucai Ge 170:11-170-18 [redacted]

3. ZHP's Failure to adequately Validate the Valsartan process change.

115. [redacted]

4. ZHP's Failure to Adequately Train Quality Assurance Personnel

117. [redacted]

[47] ZHP01427917 (August 2018 FDA Establishment Inspection Report), page 25.
[48] ZHP01427917 (August 2018 FDA Establishment Inspection Report), page 25.
[49] PRINSTON00463786.
[50] PRINSTON00463786

[redacted]

[51] PRINSTON00463786.
[52] Dep. Tr. Remonda Gergis 241:15-24.
[53] PRINSTON00368123.
[54] PRINSTON00368123.
[55] Dep. Tr. Jucai Ge 230:7-23.

[redacted]

5. ZHP's Statements Relative to Genotoxicity

[redacted]

[56] Dep. Tr. Eric Tsai 173:4-175:6.
[57] Dep. Tr. Minli Zhang. 436:13-22.
[58] Dep. Tr. Jucai Ge Dep. 313:10-317:16.
[59] Torrent-MDL2875-00005036 (ZHP Genotoxicity Statement, Lucy Liu, ZHP Manager, Regulatory Affairs, July 6, 2016).
[60] ZHP00079913, (Response to FDA DMF Information Request Letter).

ii. Evidence Common to the Class of Defendant Mylan's Non-Compliance with CGMPs

1. Mylan's Failure to Heed its Own Risk Assessment With Respect to Recovered Solvents

[redacted]

[redacted] MYLAN-MDL2875-00421388 & -389 (marked at Mr. Glover's deposition as Pl-Glover-6 & -7).
[62] MYLAN-MDL2875-00421389, at -395 (Pl-Glover-7).
[63] Dep. Tr. D. Glover 82:2-6.
[64] MYLAN-MDL2875-00421389, at -395 (Pl-Glover-7).
[65] Dep. Tr. D. Glover 855:6-13.
[66] Dep Tr. Glover 477:21-481:23; Dep. Tr. D. Snider 362:17-363:7; Dep. Tr. A. Gomas 139:2-141:4; *see also* Pl-Glover-56 & -57.
[67] (Pl-Glover 8 & 9 (MYLAN-MDL2875-00257214 & -215) [redacted] Dep. Tr. D. Glover Dep 100:6-101:3; Dep. Tr. Snider 128:14-17.

2. MYLAN'S FAILURE TO PROPERLY OVERSEE THIRD PARTY CONTRACTORS UTILIZED IN SOLVENT RECOVERY OPERATION

134. [redacted]

[68] MYLAN-MDL2875-00708138 (February 28, 2020 Unit 7 FDA Establishment Inspection Report).
[69] MYLAN-MDL2875-00708138 (February 28, 2020 Unit 7 FDA Establishment Inspection Report).
[70] MYLAN-MDL2875-00708138 (February 28, 2020 Unit 7 FDA Establishment Inspection Report), page 28.

[redacted]

iii. Evidence Common to the Class of Defendant Teva's Non-Compliance with CGMPs

144. [redacted]

[71] MYLAN-MDL2875-00708138 (February 28, 2020 Unit 7 FDA Establishment Inspection Report), page 24.
[72] APL-MDL2875-0964965, (Lantech Warning Letter).
[73] APL-MDL2875-0964965, (Lantech Warning Letter).
[74] Teva's Head of Global Compliance and corporate designee conceded that Teva, as the ANDA holder, was ultimately responsible for the contaminated VCDs that Teva sold in the United States. Daniel Barreto Dep. Tr. Apr.

[redacted]

i. TEVA FAILED TO PROPERLY OVERSEE ITS API SUPPLIERS

[redacted]

14, 2021 at 62:5 to 63:6 [redacted]

[75] TEVA-MDL-00158603; Dep. Tr. Anthony Binsol 47:14-24.
[76] TEVA-MDL-00158603; Dep. Tr. Anthony Binsol 50:1 to 51:11; TEVA-MDL2875-00399168, at -200, -238.
[77] TEVA-MDL2875-00684220; Dep. Tr. Anthony Binsol 54:2-16.
[78] TEVA-MDL2875-00259905; Dep. Tr. Anthony Binsol:8 to 61:18 [redacted]
[79] TEVA-MDL2875-00259910; Dep. Tr. Anthony Binsol 96:6 to 97:7.
[80] TEVA-MDL2875-00259910; TEVA-MDL2875-00259910; Dep. Tr. Anthony Binsol 102:4 to 103:4.
[81] Dep. Tr. Anthony Binsol 108:1 to 109:8.
[82] Dep. Tr. Anthony Binsol 121:5 to 122:21; TEVA-MDL2875-00020279, at ¶¶ 1.2, 6.6; Dep. Tr. Pan Lin 152:6-11.
[83] TEVA-MDL2875-00791611; Dep. Tr. Anthony Binsol 121:5 to 122:21.

[redacted]

[84] TEVA-MDL2875-00549883 at p.1 of 4; TEVA-MDL2875-00049024; TEVA-MDL2875-00320639 at -641.
[85] ZHP00912962.
[86] ZHP00912962.
[87] TEVA-MDL2875-0399168, at -233-245; TEVA-MDL2875-00118147, at -154; Dep. Tr. Pan Lin 72:9 to 74:23; 76:3-16; 80:9 to 82:12; 85:18 to 88:11.
[88] TEVA-MDL275-0399168, at -187; TEVA-MDL2875-00118147, at -154; Dep. Tr. Pan Lin 72:9 to 74:23.

[redacted]

iv. Evidence Common to the Class of Defendant Torrent's Non-Compliance with CGMPS

155. [redacted]

[89] TEVA-MDL2875-00415117 at Attachment 2.
[90] Dep. Tr. Daniel Barreto 74:22 to 76:23.
[91] Dep. Tr. Daniel Barreto 69:20 to 75:2, 360:15-18.
[92] TEVA-MDL2875-00247059; TEVA-MDL2875-00318831.
[93] Dep. Tr. Narendra Vadsola 319:1 to 326:9.
[94] Dep. Tr. Narendra Vadsola 318:6-18.

156. [redacted]

1. TORRENT FAILED TO OVERSEE ITS API MANUFACTURING SUPPLIER

157. [redacted]

[95] TORRENT-MDL2875-00000149; TORRENT-MDL2875-00003958 at 297-320.
[96] Dep. Tr. Jaiswal 334-335.
[97] Chitty, Dep. Tr. At 289:3-23; TORRENT-MDL2875-00004186; TORRENT-MDL2875-00072520-72526.
[98] TORRENT-MDL2875-00291311 at -33; TORRENT-MDL2875-00131251.

163. [redacted]

v. Evidence Common to the Class of Defendant Aurobindo's Non-Compliance with CGMPs

1. Aurobindo's Failure to Oversee its Solvent Recovery Vendor

167. [redacted]

[redacted]Torrent-MDL2875-00433346.
[100] APL-MDL2875-0391332, (Aurobindo Warning Letter, June 20, 2019)
[101] Dep. Tr. Ambati Rama Mohana Rao 180:4-183:19.
[102] Dep. Tr. Singh 387:15-389:4; Exhibit Rao 143 (APL-MDL 2875-0504366 at 0504398)

171. [redacted]

. [redacted]

2. Aurobindo's Failure to Competently Investigate its Products for Nitrosamines

173. [redacted]

[redacted]

[redacted]

vi. Evidence Common to the Class of Defendant Hetero's Non-Compliance with CGMPs

1. Hetero's Failure to Conduct Adequate Investigations into Manufacturing Issues or Inspections

176. [redacted]

[redacted]

[103] Dep. Tr. Rao 181:11-23.
[104] APL-MDL2875-0391332, (Aurobindo Warning Letter, June 20, 2019)
[105] HLL446173

[redacted]

2. HETERO'S FAILURE TO HAVE PROPER VALIDATION PROTOCOLS

[redacted]

3. HETERO'S FAILURE TO APPROPRIATELY TRAIN QUALITY ASSURANCE AND QUALITY CONTROL PERSONNEL

182. [redacted]

[106] HLL446173
[107] HETERO_USA000151204
[108] HLL446173
[109] HLL446173
[110] HETERO_USA000151204
[111] HETERO_USA000151204

186. [redacted]

VI. CONCLUSION

187. I have only described a small sampling of the cGMP violations that were observed at the Manufacturer Defendants' facilities from 2012 until present. I chose these examples to be demonstrative, and not exhaustive.

188. Based upon my review of the documents discussed in this report, it is obvious that each Manufacturer Defendant was observed to have serious, systemic issues related to their overall corporate quality assurance operations.

189. The FDA identified these corporate quality assurance practices and failings as contributing to the Manufacturer Defendants' Valsartan products becoming contaminated with NDMA and NDEA.

190. For the purposes of this declaration I am not opining on the ultimate question of whether these corporate level QA failings were the ultimate reason why the Manufacturer Defendants' Valsartan products contained NDMA or NDEA.

191. However, I do conclude that because of the nature of these deficiencies (being high level corporate QA failings), the corporate quality assurance deficiencies described herein are the type of quality assurance activities that would have impacted each of the Manufacturer Defendants' valsartan products equally and in the same manner.

Dated: November 7, 2021

John L. Quick

Exhibit A

Materials Relied Upon for Declaration

Documents From the Litigation

- ZHP01427917
- ZHP00000161 (and translation provided by Counsel)
- ZHP00000417
- ZHP01427950
- ZHP01748896
- ZHP02630924
- ZHP02118072
- ZHP02118712
- ZHP00912962.
- PRINSTON00463786
- PRINSTON00368123
- ZHP00079913
- Torrent-MDL2875-00005036
- TORRENT-MDL2875-00000149
- TORRENT-MDL2875-00003958
- TORRENT-MDL2875-00131251
- TORRENT-MDL2875-00004186
- TORRENT-MDL2875-00072520
- TORRENT-MDL2875-00291311
- TORRENT-MDL2875-00433346
- MYLAN-MDL2875-00421388
- MYLAN-MDL2875-00421389
- Glover Deposition Exhibit-56
- Glover Deposition Exhibit 57
- MYLAN-MDL2875-00257214
- MYLAN-MDL2875-00257215
- MYLAN-MDL2875-00708138
- APL-MDL2875-0964965
- APL-MDL2875-0391332
- APL-MDL 2875-0504366
- TEVA-MDL-00158603
- TEVA-MDL2875-00684220
- TEVA-MDL2875-00259905
- TEVA-MDL2875-00259910
- TEVA-MDL2875-00020279
- TEVA-MDL2875-00791611
- TEVA-MDL2875-00549883

- TEVA-MDL2875-00049024
- TEVA-MDL2875-00320639
- TEVA-MDL2875-0399168
- TEVA-MDL2875-00118147
- TEVA-MDL2875-00415117
- TEVA-MDL2875-00247059
- TEVA-MDL2875-00318831
- HLL446173
- HETERO_USA000151204

Depositions

Jucai Ge (ZHP)

Min Li (ZHP)

Remonda Gergis (ZHP)

Eric Tsai (ZHP)

Minli Zhang (ZHP)

Derek Glover (Mylan)

Daniel Snider (Mylan)

Antonyraj Gomas (Mylan)

Daniel Bareto (Teva)

Anthony Binsol (Teva)

Pan Lin Deposition (Teva)

Narendra Vadsola (Teva)

Sushil Jaiswal Deposiiton (Torrent)

Dawn Chitty Deposition (Torrent)

Ambati Rama Mohana Rao (Aurobindo)

Sanjay Singh (Aurobindo)

Publicly Available Documents

FDA Compliance Program Guidance Manual 7356.002F, September 11, 2015

FDA Power Point Presentation by Robert C. Horan, New York District, "*FDA cGMP Inspection, Peking University 2005"*
FDA Guidance Q10 "*Quality Systems Approach to Pharmaceutical CGP Regulations*," September 2006

FDA Guidance Q10, *"Pharmaceutical Quality System*

FDA Guidance "Contract Manufacturing Arrangements for Drugs: Quality Agreements," November 2016.

FDA Guidance, *"Control of Nitrosamine Impurities in Human Drugs,"* February 2021FDA Compliance Program Guidance Manual, API Process Inspection, September 11, 2015, page 4

FDA Presentation, "*FDA's Pre-Approval Inspection (PAI) Program and How to prepare for a successful outcome,*" Denise DiGlulio, FDA Facility Reviewer, Office of Process and Facilities, Fall 2015.

FDA Presentation, *"The Pharmaceutical Quality System (PQS),"* Robert Iser, FDA Office of Process & Facilities/OPQ/CDER, July 15, 2015.

FDA Warning Letter, Akorn, Inc. June 13, 2019, and US Pharmaceuticals, Inc. June 6, 2019.

Websites

https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda

https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps

www.fda.gov/ICECI/inspections/ucm250720.htm

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions

https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false

Exhibit

John L. Quick

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Genoa City, WI 53128

(847) 275-8770

JohnLQuick1@aol.com

SUMMARY OF QUALIFICATIONS

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EXPERIENCE

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BAXTER INTERNATIONAL, INC. **1966-2003**

Corporate VP Worldwide Quality/Regulatory reporting to Chairman and CEO 1998-2003

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Corporate VP Quality for drug, device, and cardiovascular operations 1994-1998

IV Systems VP Quality/Regulatory (Included Corporate Sterilization and Microbiology function) 1986-1994

VP Sterile Fluids Technology Group with total responsibility over all Baxter sterile fluids 1984-1986

VP Product Development and Engineering Parenteral Products 1981-1984

Director Biomedical Engineering 1977-1981

Manager Biomedical Engineering 1973-1977

Various other positions 1966-1973

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Papers, Publications, Presentations and Patents (partial listing)

i A M tr dr *Closed System Filling Technology: A New Paradigm,* A tt r b r b r

i *Management's Role in Quality Management,* t r h x i r i i r i t b r

i *International Issues in the Quality Movement,* t ti r A tr i ri t it A i ti d A tr i t b r

i *Training our Employees,* t i th t r ti d M t ri r ti r r d b th i r it r i Ath d th At t A i tri t M r h

i *Management and Leadership, Industry Perspective,* A A it t ti h i i M di i d tr r h r i i b r

i *Quality Leadership at the Top,* th A M i th i h tr A d M di i r r d t b r

i *International Movement in the Quality Scene,* th ti r A tr i ri t it A i ti b rr A tr i t b r

i *Quality and the Management Process,* tr ti it ri t bi A t r t d i i h

i *Integrating Quality into Your Business Management System,* M t r r A i i it i i r i M

i *Integrating Quality into Your Business Management System,* r rd it r A ri

i *Baxter Healthcare Corporation's Approach to Ethics and Corporate Compliance,* Ar i t i di M di i M t r r i r di i di t b r

i *Corporate Compliance Audits, A Management Perspective,* r r t i A dit r t ti r r d it i r d h r h d r hi t

Issued Patents

M th d *for Adding Medicaments to a Sealed Expandable Parenteral Fluid Container,* M r h

Vial and Syringe Connector, A t

Process for Sterilizing and Transferring a Solution, b r